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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,358	06/08/2000	Narendra Raghunathji Desai	273012008102	2416

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/589,358

Applicant(s)

DESAI ET AL.

Examiner

Gollamudi S Kishore, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The amendment and 1.131(a) declaration dated 1-28-04 are acknowledged.

Claims included in the prosecution are 15-38.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 15-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,074,666. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth before.

Applicants indicated their willingness to file a terminal disclaimer in their previous response. The rejection is maintained in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 15-20 and 30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Madden (5,389,378).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Madden does not teach the presence of a sugar. This argument is not found to be persuasive since Madden clearly teaches the presence of a sugar as evident from his teachings on col. 9, lines 16-30 and Example 1 on col. 12. Applicant argues that instant claims require that the formulations have an osmolarity of human blood. This argument is not found to be persuasive since Madden on col. 10 teaches that the formulations are isotonic (meaning that the osmolarity is the same as blood).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 15-18, 20-25 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden cited above.

Madden discloses Benzoporphyrins encapsulated in liposomes for photodynamic therapy of various cancers. The preparation is in a freeze-dried form and contains lactose. Madden teaches the use of a mixture of phospholipids and the lipids include DMPC and PG (note the abstract, col. 5, line 54 through col. 8, line 64, col. 9, lines 1 through line 62, Examples, Example 1 in particular and claims). What are lacking in Madden are the teachings of claimed range of sizes. However, Madden teaches a size of 120 nm, which is closer to the lower size range of about 130 nm. In the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to manipulate the sizes of the liposomes to obtain the best possible results. Such a skill is within the skill of the art. Madden also does not disclose the amounts of sugar in all of

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the claimed ratios. However, in view of Madden's teachings of the isotonic nature of the composition, it is deemed obvious to manipulate the amounts of the sugars and still achieve the isotonic nature of the composition as taught by Madden.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Madden teaches away since the liposome sizes are less than the claimed sizes. This argument is not persuasive since as pointed out above, sizes are manipulatable parameters and applicant has not shown any unexpected findings resulting from the increased liposomal sizes.

7. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden as set forth above, further in view of Barenholz (4,797,285) already of record.

What is lacking in Madden is the teaching of inclusion of an antioxidant such as BHT.

Barenholz while disclosing drug-containing liposomes, teaches that the inclusion of free-radical scavengers will prevent the oxidation of the compounds (note the abstract and col. 10, line 49 through col. 11, line 34).

The inclusion of a free-radical scavenger such as BHT in Madden would have been obvious to one of ordinary skill in the art since such an inclusion would prevent the oxidation of active agents as taught by Barenholz.

Applicant's arguments that there is no motivation to combine are not found to be persuasive since Barenholz is combined for its teachings of prevention of oxidation by the antioxidants.

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8. Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden as set forth above, further in view of applicant's statements of prior art.

Madden does not teach all the porphyrin derivatives recited in instant claims. Instant specification appears to indicate that the claimed porphyrin derivatives are known. The use of art known porphyrin derivatives in the liposomes of Madden, or Thompson or Kappas with the expectation of obtaining similar results would have been obvious to one of ordinary skill in the art from the guidance provided by the prior art.

This rejection is maintained since applicant provides no specific arguments for this rejection.

9. Claims 15-18, 20-25 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (5,277,913) or Kappas (5,010,073) in view of Crowe (4,857,319), further in view of Madden cited above.

Both Thompson and Kappas teaches liposomal porphyrins and photodynamic therapy (note the abstracts, Examples and claims in each).

What is lacking in these references is the teaching of the presence of sugars. What is also lacking in these references is the teaching that the osmolarity of the composition be the same of blood.

Crowe teaches that sugars protect liposomes during dehydration and rehydration (note the abstract, examples and claims).

Madden as discussed above, teaches that when the liposomal compositions containing the porphyrins are administered parenterally, the compositions are and this

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could be achieved by the addition of salts, glucose or dextrose isotonic (note col. 10, lines 27-30).

The use of sugars in the liposomes of Thompson, and Kappas would have been obvious to one of ordinary skill in the art since sugars preserve liposomes during dehydration and rehydration steps. The addition of sugars would also have been obvious to one of ordinary skill in the art since these compounds are also helpful in making the compositions isotonic as taught by Madden.

10. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (5,277,913) or Kappas (5,010,073) in view of Crowe (4,857,319) and Madden as set forth above, further in view of Barenholz (4,797,285) already of record.

The teachings of Thompson, Kappas, Crowe and **Madden have been discussed above.**

What is lacking in these references is the teaching of inclusion of an antioxidant such as BHT.

Barenholz while disclosing drug-containing liposomes, teaches that the inclusion of free-radical scavengers will prevent the oxidation of the compounds (note the abstract and col. 10, line 49 through col. 11, line 34).

The inclusion of a free-radical scavenger such as BHT would have been obvious to one of ordinary skill in the art since such an inclusion would prevent the oxidation of active agents as taught by Barenholz.

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11. Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (5,277,913) or Kappas (5,010,073) in view of Crowe (4,857,319) as set forth above, further in view of applicant's statements of prior art.

Neither Madden, Thompson nor Kappas teach all the porphyrin derivatives in instant claims. Instant specification appears to indicate that the claimed porphyrin derivatives are known. The use of art known porphyrin derivatives in the liposomes of Madden, or Thompson or Kappas with the expectation of obtaining similar results would have been obvious to one of ordinary skill in the art from the guidance provided by the prior art.

Claims 37 and 38 are allowable once the terminal disclaimer is filed Claims 19 and 26 are allowable if written in an independent form and when the terminal disclaimer is filed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1234.



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK